

PROTECTING PUBLIC HEALTH

Ensuring Compliance With Federal Tobacco Product Regulation

EVERY DAY IN THE UNITED STATES:



1,300+
people die each
day due to
cigarette use¹



2,600+
youth under age 18 smoke
their first cigarette, and nearly
1,300 use smokeless tobacco
for the first time²



Nearly **600**
youth under age 18 become
daily cigarette smokers²

Creating Powerful Change for a Healthier Future

To protect the public, especially youth, from the dangers of tobacco use, the Center for Tobacco Products (CTP) Office of Compliance and Enforcement (OCE) ensures that regulated industry complies with federal tobacco product regulation using a three-pronged approach:

- 1** Develop and provide compliance training and education.
- 2** Monitor regulated industry's compliance with the law through surveillance, inspections, and investigations.
- 3** Initiate advisory and enforcement actions such as issuing warning letters and seeking Civil Money Penalties against noncompliant industry, as appropriate.

Compliance and enforcement activities include, but are not limited to:



Inspecting manufacturing facilities and retail establishments



Reviewing industry submissions, registrations, and listings



Reviewing print and online advertising



Handling potential violation complaints from the public



Monitoring promotional activities



Educating retailers and small businesses on federal tobacco regulations

When CTP observes a violation, CTP takes action. We generally issue a Warning Letter to a company for first-time violations. CTP may subsequently initiate enforcement action for companies that continue to violate the law, such as:

- Civil money penalty (fine)
- No-tobacco-sale order
- Seizure
- Injunction
- Criminal prosecution

Enforcing the Law

As of April 1, 2016:



590,000
inspections of tobacco
retailers have been conducted.



43,100
Warning Letters have been
issued to retailers
following compliance
check inspections.



6,955
Civil Money Penalties
have been issued
to retailers for
violating the law.



380
Warning Letters have
been issued to online
retailers stemming from
surveillance activities.

Ensuring That Tobacco Products Stay Out of the Hands of Kids

To help end youth access to tobacco products, OCE investigates complaints from the public about potential violations.

The public plays a vital role in helping us to identify possible violations of the laws we enforce. Protect kids by watching out for these violations, such as:



- Sales of cigarettes or smokeless tobacco to minors
- Sales of single cigarettes



- Sales of flavored cigarettes or flavored cigarette tobacco (except menthol)



- Offers of free samples of cigarettes
- Offers of free samples of smokeless tobacco, unless in a "qualified adult-only facility"

Reporting Violations to Help CTP



Fill out the Potential Tobacco Product Violations Reporting Form



Call the Tobacco Call Center toll-free at 1.877.CTP.1373



Send us a letter at:

Document Control Center
Center for Tobacco Products
Food and Drug Administration
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993



Email us at
CTPCompliance@FDA.hhs.gov

Determining a Course of Action

After FDA reviews a complaint, next steps may include:



Performing an inspection of a tobacco product manufacturer, distributor, or importer



Conducting a compliance check inspection of a tobacco retailer



Initiating monitoring and surveillance of a tobacco product manufacturer's or retailer's website

Additional Resources

- FDA.gov/tobacco
- [FDA Warning Letters](#)
- [Retailer Inspection Database](#)

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¹ U.S. Department of Health and Human Services. *The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2014.

² Substance Abuse and Mental Health Services Administration (SAMHSA). *Results from the 2012 National Survey on Drug Use and Health*, NSDUH: Table 4.10A Past Year Initiation of Substance Use among Persons Aged 12 or Older Who Initiated Use Prior to the Age of 18, by Gender: Numbers in Thousands, 2013 and 2014. Rockville, MD: U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, 2015. Retrieved on October 20, 2015, from <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.pdf>.



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